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- (ii) Reconsideration of the initial denial determination;
- (4) The locations for filing a request for reconsideration or review and the time period within which a request must be filed;
- (5) A statement about who is liable for payment of the denied services under section 1879 of the Act; and
- (6) A statement concerning the duties and functions of the QIO under the Act.
- (d) Notice to payers. The QIO must provide prompt written notice of an initial denial determination or changes as a result of a DRG validation to the Medicare administrative contractor, fiscal intermediary, or carrier within the same time periods as the notices to the other parties.
- (e) Record of initial denial determination and changes as a result of a DRG validation. (1) The QIO must document and preserve a record of all initial denial determinations and changes as a result of DRG validations for six years from the date the services in question were provided.
- (2) The documentary record must include—
- (i) The detailed basis for the initial denial determination or changes as a result of a DRG validation; and
- (ii) A copy of the determination or change in DRG notices sent to all parties and identification of each party and the date on which the notice was mailed or delivered.
- [50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68561, Nov. 15, 2012]

# § 476.96 Review period and reopening of initial denial determinations and changes as a result of DRG validations.

- (a)  $General\ time frame.$  A QIO or its subcontractor—
- (1) Within one year of the date of the claim containing the service in question, may review and deny payment; and
- (2) Within one year of the date of its decision, may reopen an initial denial determination or a change as a result of a DRG validation.
- (b) Extended timeframes. (1) An initial denial determination or change as a result of a DRG validation may be made after one year but within four years of

- the date of the claim containing the service in question, if CMS approves.
- (2) A reopening of an initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the QIO's decision if—
- (i) Additional information is received on the patient's condition;
- (ii) Reviewer error occurred in interpretation or application of Medicare coverage policy or review criteria:
- (iii) There is an error apparent on the face of the evidence upon which the initial denial or DRG validation was based; or
- (iv) There is a clerical error in the statement of the initial denial determination or change as a result of a DRG validation.
- (c) Fraud and abuse. (1) A QIO or its subcontractor may review and deny payment anytime there is a finding that the claim for service involves fraud or a similar abusive practice that does not support a finding of fraud.
- (2) An initial denial determination or change as a result of a DRG validation may be reopened and revised anytime there is a finding that it was obtained through fraud or a similar abusive practice that does not support a finding of fraud.

## § 476.98 Reviewer qualifications and participation.

- (a) Peer review by physician. (1) Except as provided in paragraph (a)(2) of this section, each person who makes an initial denial determination about services furnished or proposed to be furnished by a licensed doctor of medicine or osteopathy or by a doctor of dentistry must be respectively another licensed doctor of medicine or osteopathy or of dentistry in the QIO area.
- (2) If a QIO determines that peers are not available to make initial denial determinations, a doctor of medicine or osteopathy may make denial determinations for services ordered or performed by a doctor in any of the three specialties.
- (3) For purposes of paragraph (a)(1) of this section, individuals authorized to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands

- as "medical officers" may make determinations on care ordered or furnished by their peers but not on care ordered or furnished by licensed doctors of medicine or osteopathy.
- (b) Peer review by health care practitioners other than physicians. Health care practitioners other than physicians may review services furnished by other practitioners in the same professional field.
- (c) *DRG validation review*. Decisions about procedural and diagnostic information must be made by physicians. Technical coding issues must be reviewed by individuals with training and experience in ICD-9-CM coding.
- (d) Persons excluded from review. (1) A person may not review health care services or make initial denial determinations or changes as a result of DRG validations if he or she, or a member of his or her family—
- (i) Participated in developing or executing the beneficiary's treatment plan;
- (ii) Is a member of the beneficiary's family: or
- (iii) Is a governing body member, officer, partner, 5 percent or more owner, or managing employee in the health care facility where the services were or are to be furnished.
- (2) A member of a reviewer's family is a spouse (other than a spouse who is legally separated under a decree of divorce or separate maintenance), child (including a legally adopted child), grandchild, parent, or grandparent.
- [50 FR 15330, Apr. 17, 1985, as amended at 77 FR 68561, Nov. 15, 2012]

### § 476.100 Use of norms and criteria.

- (a) Use of norms. As specified in its contract, a QIO must use national, or where appropriate, regional norms in conducting review to achieve QIO contract objectives. However, with regard to determining the number of procedures selected for preadmission review, a QIO must use national admission norms.
- (b) *Use of criteria*. In assessing the need for and appropriateness of an inpatient health care facility stay, a QIO must apply criteria to determine—
- (1) The necessity for facility admission and continued stay (in cases of

- day outliers in hospitals under prospective payment);
- (2) The necessity for surgery and other invasive diagnostic and therapeutic procedures; or
- (3) The appropriateness of providing services at a particular health care facility or at a particular level of care. The QIO must determine whether the beneficiary requires the level of care received or whether a lower and less costly level of care would be equally effective
- (c) Establishment of criteria and standards. For the conduct of review a QIO must—
- (1) Establish written criteria based upon typical patterns of practice in the QIO area, or use national criteria where appropriate; and
- (2) Establish written criteria and standards to be used in conducting quality review studies.
- (d) Variant criteria and standards. A QIO may establish specific criteria and standards to be applied to certain locations and facilities in the QIO area if the QIO determines that—
- (1) The patterns of practice in those locations and facilities are substantially different from patterns in the remainder of the QIO area; and
- (2) There is a reasonable basis for the difference which makes the variation appropriate.

## § 476.102 Involvement of health care practitioners other than physicians.

- (a) Basic requirement. Except as provided in paragraph (b) of this section, a QIO must meet the following requirements:
- (1) Consult with the peers of the practitioners who furnish the services under review if the QIO reviews care and services delivered by health care practitioners other than physicians.
- (2) Assure that in determinations regarding medical necessity of services or the quality of the services they furnish, these practitioners are involved in—
- (i) Developing QIO criteria and standards:
- (ii) Selecting norms to be used; and (iii) Developing review mechanisms
- for care furnished by their peers.
  (3) Ensure that an initial denial determination or a change as a result of